UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,744	10/18/2004	Anderson Joseph Ryan	056291-5184	6714

9629 7590 01/04/2008

MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER	
HUGHES, ALICIA R	
ART UNIT	**PAPER NUMBER**
1614	

MAIL DATE	DELIVERY MODE
01/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,744	RYAN, ANDERSON JOSEPH	
	Examiner	Art Unit	
	Alicia R. Hughes	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1 sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 3-6 are pending. Claims 1-2 and 7-12 were cancelled in the Applicant's response filed on 24 September 2007. Applicant's arguments filed on 24 September 2007 in response to the non-final rejection filed by this Office on 23 March 2007 have been fully considered, but they are not deemed to be persuasive.

Rejections not reiterated from previous office actions are hereby withdrawn. The following rejections are reiterated and arguments newly applied, and they constitute the complete set of rejections being applied to the instant application presently.

Claim Rejections – 35 U.S.C. §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3-6 are rejected under 35 U.S.C. 103(a) as being obvious over WO 01/74368 A1 [hereinafter referred to as "Davis, et al"] in view of Harari, P., et al., *Radiation Response Modification Following Molecular Inhibition of Epidermal Growth Factor Receptor Signaling*, Seminars in Radiation Oncology, vol. 11, no. 4, October 2001, pages 281-289 [hereinafter referred to as "Harari, et al."]

Applicant argues that a motivation or suggestion to combine the teachings of Davis et al with the teachings of Harari et al is lacking and that there is no teaching or implication of

combining ZD6126 and ZD1839 specifically. Moreover, that the reference to Miyata, et al, if relied upon for prior art purposes, is inapplicable, because it carries a date subsequent to the priorty date of the instant application. Applicant also argues that references must be considered in total and that when so doing with prior art references in the instant application, the Office has not established a *prima facie* case of obviousness against the instantly contemplated claims.

As noted previously, Davis et al. teach a method for the production of vascular damaging effect and a method for the treatment of cancer in a warm-blooded animal which comprises the administration of an effective amount of ZD6126 or a pharmaceutically acceptable salt thereof in a combination therapy before, after or simultaneously with an effective amount of a taxane, ionizing radiation or a platinum anti-tumor agent (Page 4, lines 20-25 – Page 6, lines 1-12; see also page 11, lines 29-31 and page 12, lines 1-30).

Davis et al. also teach use of the same combinations in the manufacture of a medicament for use in the production of an anti-cancer effect or a vascular damaging effect in warm-blooded animals either with or without ionizing radiation (Page 10, lines 1-29, page 11, lines 1-21; see also page 11, lines 29-31 and page 12, lines 1-30) and a pharmaceutical composition and a kit which comprises ZD6126 or a pharmaceutically acceptable salt and either a platinum anti-tumor agent or a taxane in a pharmaceutically acceptable carrier (Page 8, lines 14-18 and lines 24-31; see also page 11, lines 29-31 and page 12, lines 1-30).

Harari et al teach ZD1839, well-known in the art as an anti-tumor agent for many cancers (Miyata, H. et al., *The Effects Of ZD1839 (Iressa), A Highly Selective EGFR Tyrosine Kinase Inhibitor, As A Radiosensitiser In Bile Duct Carcinoma Cell Lines*, International Journal of

Oncology, vol. 28, 2006 pages 915-921), as a small molecule tyrosine kinase inhibitor (page 282, col. 1, lines 29-41) that when combined with chemotherapy or selected chemotherapy agents has the capacity to enhance the cytotoxicity of radiation across a spectrum of human cancer cell lines (Page 283, col. 2, lines 16-26, page 284, and page 285, col. 1, lines 1-4).

Contrary to Applicant's assertion, as noted previously, a motivation to combine the references is present, because Davis et al and Harari, et al. teach overlapping subject matter, most notably, the treatment of cancer and cancer treatment-related conditions with chemotherapeutic and anti-cancer agents. Further, "[i]t is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose." *In re Kerkhoven*, 205 USPQ 1069. Both ZD1839 and ZD6126, as noted prior, are anti-tumor agents. Thus, the combination of the two for the purposes set forth in this application, are *prima facie* obvious. The citation of Miyata et al in the body of the rejection does nothing to diminish this fact, most especially because it is known in the art that a chemical is inseparable from its properties. Harari et al establishes that ZD1839 was known to exist before the filing of the instant application, a new use for a known compound is not, *per se*, obvious.

In light of the foregoing, most especially when looking at the disclosed references in total, one of ordinary skill in the art would be motivated to apply the teachings of Harari et al. and Davis et al to the present invention, because ZD1839 is anti-tumor agent that when combined with other anti-cancer agents and/or ionizing radiation, effectively treats cancerous tumors through EGFR signal modulation and ZD6126 is known to produce vascular damaging effects and to treat cancer involving solid tumors. When used together, it would be obvious to

one of ordinary skill in the art that the proliferation of cancers and their associated tumors, would be diminished and vascular damaging effects enhanced through the combination therapy of ZD6126 and ZD1839 with ionizing radiation.

In light of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art to combine of ZD6126 and ZD1839 to treat cancer and enhance vascular damaging effects.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant's request for a copy of Raben D, et al. (2000) has been considered and is denied, because the same did not establish the basis for or per se, further support the rejection herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR of Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see http://pair-direct-uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

31 December 2007

Alicia Hughes

Ardin H. Marschel 12/30/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER